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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/701,990	11/04/2003	Marc K. Hellerstein	416272005200	6654

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EXAMINER	
VENCI, DAVID J	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 09/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/701,990	HELLERSTEIN, MARC K.	
	Examiner	Art Unit	
	David J. Venci	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *May 9, 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-66* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-32, 34-35 and 37-43, drawn to a method of detecting ^{2}H incorporation into water (hereinafter "BASE METHOD") to determine sugar or fatty acid metabolism (hereinafter "DERIVED METHOD"), classified in class 424/1.73, for example.

II. Claim 33, drawn to a method invoking DERIVED METHOD to screen a drug, classified in class 424/9.2, for example.

III. Claim 36, drawn to an method invoking DERIVED METHOD to diagnose insulin resistance or diabetes, classified in class 436/811, for example

IV. Claims 44-48, 50 and 61-64, drawn to products comprising sugar, classified anywhere in class 127, for example.

V. Claim 49, drawn to a drug, classified anywhere in class 514, for example.

VI. Claim 59, drawn to a perturbed agent, classified anywhere in the class 532-570 series, for example.

VII. Claims 52-58, drawn to a device, classified in class 162/100, for example.

VIII. Claims 50 and 60, drawn to products comprising fatty acid, classified in class 554/1, for example.

IX. Claims 65-66, drawn to water, classified in class 423/580.2, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II and III are related processes. Related inventions are distinct from each other if the inventions, as claimed, are not: (1) overlapping in scope, i.e., are mutually exclusive; (2) obvious variants; and (3) capable of use together or have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j).

With respect to (1), *supra*, the inventive feature of Inventions I, II and III appears to be DERIVED METHOD. However, the scope of Inventions I, II and III does not overlap because DERIVED METHOD is implemented differently in each Invention. For example, Inventions I requires a step of administering ^{2}H-

labeled sugars or ^{2}H-labeled fatty acids to an individual, while Invention II requires administering a drug agent to an individual, while Invention III requires a diagnostic correlation.

With respect to (2), *supra*, Inventions I, II and III are not obvious variants because said ^{2}H-labeled sugars, ^{2}H-labeled fatty acids and drug agents have different ADME properties, which may, or may not, be irrelevant in diagnosing insulin resistance or diabetes. Furthermore, there is no indication on the record that the Inventions would have been obvious variants over each other within the meaning of 35 U.S.C. 103(a).

With respect to (3), *supra*, Inventions I, II and III have different modes of operation and different functions because Invention I requires, *inter alia*, administering ^{2}H-labeled sugars or ^{2}H-labeled fatty acids to an individual in order to detect ^{2}H incorporation into water, while Invention II requires, *inter alia*, administering a drug agent to an individual in order to screen a drug, while Invention III requires, *inter alia*, a diagnostic correlation.

Examination burden is established because the scope of prior art search required for each Invention does not appear coextensive. For example, a search for the ADME properties of sugars or fatty acids of Invention I requires a search of prior art related to glycolysis, while a search for the ADME properties of drug agents of Invention II requires a search of prior art related to the pharmaceutical industry, while a search for the diagnostic correlation of Invention III requires a search of prior art related to diabetes.

Inventions IV, V, VI, VII, VIII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the inventions have different designs. For example, Invention IV requires sugar, while Invention V requires drugs, while Invention VI perturbed

agents, while Invention VII requires a device, while Invention VIII requires fatty acids, while Invention IX requires water.

Inventions (I, II or III) and (IV, V or VIII) are related as products and processes of using said products.[1] The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product can be practiced with another materially different product or (2) the product can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the processes of Invention (I, II or III) can be practiced with another materially different product, such as a magnetic field generator.

Inventions (I, II or III) and VII are related as processes and apparatus used in its practice.[2] The inventions are distinct if it can be shown that either: (1) the processes as claimed can be practiced with another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the data resulting from the process of Inventions (I, II, or III) can be stored with another materially different apparatus, such as by hand (brain memory).

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[1] Examiner requires restriction between product and process claims. Where Applicant elects to prosecute claims directed to a product, and the product claims are subsequently found allowable, Examiner will consider withdrawing the instant restriction requirement and rejoining non-elected, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claims (*i.e.*, all the process claims must include all the limitations of the allowable product claims). Examiner will not rejoin non-elected, withdrawn process claims that are not commensurate in scope with the allowable product claims. See MPEP § 821.04(b). Thus, where Applicant elects to prosecute claims directed to a product, Examiner advises Applicant to continually amend the non-elected, withdrawn process claims during prosecution to require all the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Upon rejoinder, Examiner will fully examine the rejoined process claims in accordance with 37 CFR 1.104 for compliance with all criteria for patentability, including the requirements of 35 U.S.C. 101, 102, 103 and 112. Examiner further advises Applicant that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where Examiner withdraws the restriction requirement before the patent issues. See MPEP § 804.01.

[2] *Id.*

Inventions (I, II or III) and (VI or IX) are related as processes of making and products made.[3] The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the products of Inventions (VI or IX) can be isolated by another materially different process, such as a liquid-liquid extraction process.

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[3] *Id.*

This application contains claims directed to the following patentably distinct species:

A. Select ONE additional analyte from:

1. ^{2}H-labelled glucose; (claims 1, 13-17 and 29)
2. ^{2}H-labelled glycogen; (claims 1, 13, 18 and 29)
3. ^{2}H-labelled glycerol-triglyceride; (claims 1, 13, 19-20 and 29)
4. ^{2}H-labelled triglyceride-fatty acid; (claims 1, 13, 21-24 and 29)
5. ^{2}H-labelled protein; (claims 13, 25 and 29)
6. ^{2}H-labelled DNA; OR (claims 13, 26 and 29)
7. ^{2}H-labelled fatty acids and ^{2}H-labelled DNA. (claims 1, 13, 21-24, 26-27 and 29)

B. Select ONE examination from:

1. insulin resistance diagnostic; (claims 1 and 36-37)
2. diabetes mellitus diagnostic; (claims 1 and 36-37)
3. high-fat diet-induced obesity diagnostic; (claims 1 and 38-39)
4. wasting disorders diagnostic; (claims 1 and 41)
5. hypoglycemia diagnostic; (claims 1 and 42)
6. glycogen storage disease diagnostic; (claims 1 and 43)
7. insulin resistance intervention; (claims 1 and 40)
8. diabetes mellitus intervention; (claims 1 and 40)
9. high-fat diet-induced obesity intervention; (claims 1 and 40)
10. wasting disorders treatment; (claims 1 and 41)
11. hypoglycemia treatment; OR (claims 1 and 42)
12. glycogen storage disease treatment. (claims 1 and 43)

C. Select ONE sample from:

1. blood (claim 9);
2. urine (claim 9);

3. saliva (claim 9);
4. tears (claim 9);
5. liver (claim 10);
6. muscle (claim 10);
7. adipose (claim 10);
8. intestine (claim 10);
9. brain (claim 10); OR
10. pancreas (claim 10).

Applicant is required under 35 U.S.C. 121 to elect ONE species from each of species groups A, B and C, *supra*. Prosecution on the merits shall be restricted to the elected species if no generic claim is finally held allowable.

Currently, claims 1, 33, 44, 50 and 60 are generic. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

With respect to species group A, above, the species are independent or distinct because compounds (A)(1) to (A)(7) require different isolation/purification/detection protocols. With respect to species group B, above, the species are independent or distinct because each examination requires different individuals and different steps. With respect to species group C, above, the species are independent or distinct because each sample type may require different sample processing methods/devices, or different analyte isolation and detection schemes.

Applicant is advised that a complete reply to this requirement must include: (i) an election of a species or invention to be examined even if the requirement is traversed[4] (37 CFR 1.143), and (ii) identification of the claims encompassing the elected invention.

As indicated, *supra*, restriction for examination purposes is proper because the inventions are distinct and require separate, non-coextensive searches of the prior art.

Examiner unsuccessfully attempted to contact Michael Ward on July 12, 2006, for a telephone election to this Restriction Requirement.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

David J Venci
Examiner
Art Unit 1641

djv

Long

LONG V. LE 09/15/06
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

[4] Applicant may elect an invention or species with traverse or without traverse. To reserve a right to petition either election, Applicant must elect with traverse. Should Applicant traverse on the ground that the inventions or species are not patentably distinct, Applicant should clearly admit on the record, or submit or identify evidence on the record that the inventions or species are obvious variants. If Examiner finds one Invention unpatentable over the prior art, Examiner may use the evidence or admission of record to reject other inventions under 35 U.S.C.103(a).